

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: WAVE 3 CASES	

**RESPONSE IN OPPOSITION TO PLAINTIFFS’ MOTION TO EXCLUDE
OR LIMIT THE OPINIONS AND TESTIMONY OF DR. SHELBY THAMES**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”) submit this response to Plaintiffs’ Motion [ECF 2839 (“Mot.”)] and Memorandum of Law in Support of Plaintiffs’ Motion to Exclude the Opinions and Testimony of Shelby Thames, Ph.D. [ECF 2841 (“Mem.”)] (collectively, the “Motion”). This Response applies to the cases identified in Exhibit A to Plaintiffs’ Motion.

I. Adoption of Response.

In their Motion, Plaintiffs adopted their Wave 2 *Daubert* motion regarding Dr. Thames. Mot. at 1. In response, Ethicon hereby adopts and incorporates by reference its *Daubert* Response in Opposition to Plaintiffs’ Motion to Exclude the Opinions and Testimony of Shelby Thames, Ph.D. for Ethicon Wave 2 [ECF No. 2553] (“Wave 2 Resp.”).

In addition, this Court denied Plaintiffs’ Wave 1 *Daubert* motion on all grounds, with the exception that Dr. Thames’s “occasional[] misstate[ment]” that Ethicon’s seven year dog study reported no molecular weight change. Mem. Op. and Order (*Daubert* Motion re: Shelby Thames, Ph.D.) (S.D. W. Va. Sept. 2, 2016) [ECF No. 2723] (“Wave 1 Thames Order”). To the extent

that Plaintiffs advance the same arguments they put forward in Wave 1, the Court should deny Plaintiffs' motion for the reasons articulated in its Wave 1 Order.

II. Dr. Thames Can Offer Opinions Based on His Cleaning Protocol Because Plaintiffs' Additional Arguments Are Limited to His Supplemental Report.

This Court has denied Plaintiffs' Wave 1 challenge to Dr. Thames's cleaning protocol. *See* Wave 1 Thames Order at 7. In their Wave 2 motion—which Plaintiffs adopted in Wave 3—Plaintiffs attacked Dr. Thames's cleaning protocol on the same basic grounds they put forward in their Wave 1 motion. *See* Mem. in Supp. of Pls.' Mot. to Exclude Certain Opinions of Dr. Shelby Thames, at 17-20 [ECF 2458] ("Wave 2 Mem.").¹ The Court should deny Plaintiffs' Wave 3 challenge to Dr. Thames's cleaning protocol for the same reasons articulated in its Wave 1 Thames Order.

Although Plaintiffs advanced some additional arguments in their Wave 3 memorandum of law, all of their arguments are limited to Dr. Thames's supplemental report. *See, e.g.*, Mem. at 2 (arguing only that "any opinions garnered from [Dr. Thames's supplemental report] should be excluded from trial"). Plaintiffs made no challenges to the cleaning protocol itself. For this reason, even if the Court precludes Dr. Thames from offering opinions based on his supplemental report, he should still be permitted to testify about his cleaning protocol consistent with the Court's Wave 1 Thames Order.

¹ The only substantive difference is that in Wave 2, Plaintiffs pointed to a study by Celine Mary for the proposition that "peer reviewed literature from 1998 described that stresses like shaking and sonication would remove the outer degraded layer from explanted Prolene." Wave 2 Mem. at 17 (quoting Mot. Ex. D, C. Mary, *et al.*, *Comparison of the In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery*, 44 ASAIO J. 199 (1998)). But, as explained in Ethicon's Wave 2 Response, the Mary study's cleaning protocol did not use sonication or shaking. *See* Wave 2 Resp. at 18; *see also* Mot. Ex. D, Mary, at 200-02. In fact, the Mary study's cleaning protocol is entirely distinct from the methods used by Dr. Thames. *Compare* Mot. Ex. D, Mary, at 200-02 *with* Mot. Ex. B, Thames Report at 103-04. For this reason, the Mary study simply does not support Plaintiffs' assertion that Dr. Thames's cleaning protocol removes evidence of oxidation.

III. Plaintiffs' Additional Arguments Are Meritless.

In order to address allegations advanced by Plaintiffs in prior Wave cases, Dr. Thames conducted a simple test to assess whether his cleaning protocol “removes oxidation products formed and/or residing on Prolene’s surface.” Mot. Ex. C, Intentional Oxidation of Prolene Mesh, Supplemental Report of Dr. Shelby F. Thames at 9 (Aug. 8, 2016) (“Thames Supp. Report—Part 1”); Resp. Ex. A, Intentional Oxidation of Prolene Mesh—Part 2, Supplemental Report of Dr. Shelby F. Thames at 9 (Sept. 28, 2016) (“Thames Supp. Report—Part 2”). To do so, Dr. Thames intentionally oxidized a sample of Prolene mesh using ultraviolet (“UV”) light, a well-established method for oxidizing all forms of polypropylene. Resp. Ex. A, Thames Supp. Report—Part 2 at 1; *see also* Thames General Report at 4 (explaining that the “structure of Prolene and/or PP can be altered by exposure to ultraviolet radiation.”). In order to ensure oxidation, Dr. Thames subjected the sample to UV light for 500 hours. Resp. Ex. A, Thames Supp. Report—Part 2 at 1, 6-7.

Dr. Thames then subjected the intentionally oxidized mesh to certain elements of his cleaning protocol. Dr. Thames’s initial supplemental report addressed Steps 1 through 4 of his cleaning protocol, and expressly advised Plaintiffs that the “oxidized Prolene exemplar is currently being processed through the cleaning steps of Figure 1, and that data will be reported when complete.” Mot. Ex. C, Thames Supp. Report—Part 1 at 12. Plaintiffs chose not to depose Dr. Thames on his supplemental report.

Dr. Thames subsequently completed Steps 5 through 23 of his cleaning protocol, and submitted his data to Plaintiffs in Part 2 of his supplemental report. *See generally* Resp. Ex. A, Thames Supp. Report—Part 2. As Dr. Thames noted in Part 2 of his supplemental report, his decision to expose the mesh sample to UV light for 500 hours resulted in an extremely brittle

sample. *Id.* at 8, 11. For this reason, and to ensure that he was able to generate some usable data, Dr. Thames elected to omit the ultrasonication steps from his cleaning protocol for the purposes of the supplemental test. *Id.* at 11. Dr. Thames also omitted the use of Proteinase K from his supplemental tests because it is an enzyme that is known to denature proteins which has no effect on synthetic polymers like Prolene. Because the Prolene filament used in the test was a pristine exemplar that had never been exposed to proteins, the use of Proteinase K was unnecessary.

Ethicon states that Dr. Thames will not opine at trial that the test proves that his cleaning protocol does not or cannot eliminate evidence of oxidation on Prolene. Rather, Dr. Thames will testify that he has conducted a test on a Prolene mesh using certain elements of his cleaning protocol, and that this test showed no reduction in oxidation on that mesh. Dr. Thames will further testify that his cleaning protocol is the product of fundamental principles of polymer science, generally accepted analytical tools, as well as his over 50 years of education, training, and experience as a polymer scientist. Dr. Thames will also explain that he has seen no testing or data—from Plaintiffs’ experts, the scientific literature, or anywhere else—that supports the notion that his cleaning protocol removes or reduces evidence of oxidation.

In their Motion, Plaintiffs challenge Dr. Thames’s supplemental report as unfinished, statistically unreliable, and scientifically sound and irrelevant. Mem. at 2. Notably, Plaintiffs fail to identify any scientific support whatsoever to support their assertions. Instead, they offer only the speculative assertions of Plaintiffs’ counsel. The Court should deny Plaintiffs’ motion on this basis alone.

A. Dr. Thames Supplemental Test is Complete.

Plaintiffs assert that the Court should exclude Dr. Thames's opinions based his supplemental report because it addresses "an unfinished experiment." Mem. at 2. Plaintiffs' argument lacks merit because Dr. Thames has submitted Part 2 to his supplemental report.

To the extent Plaintiffs argue that Part 2 of Dr. Thames's supplemental report is untimely, Ethicon respectfully submits that Dr. Thames's supplemental report was properly served pursuant to the Federal Rules of Civil Procedure. The Federal Rules of Civil Procedure expressly obligate an expert witness to supplement his report with new information. *Compare* Fed. R. Civ. P. 26(e)(2) ("For an expert whose report must be disclosed under Rule 26(a)(2)(B), the party's duty to supplement extends [] to information included in the report. . . . Any additions or changes to this information must be disclosed *by the time the party's pretrial disclosures under Rule 26(a)(3) are due.*") (emphasis added), *with* PTO # 210, at 2 ("The last date to complete depositions shall be the 'discovery completion date' by which all discovery, including disclosures required by Federal Rule of Civil Procedure 26(a)(1), and (2), *but not disclosures required by Federal Rule of Civil Procedure 26(a)(3), shall be completed.*") (emphasis added) [ECF 1824]. In other words, the test results represent Ethicon's compliance with its duty to supplement information.

In addition, Plaintiffs cannot claim surprise with respect to Part 2 of Dr. Thames's supplemental report because he expressly informed Plaintiffs in Part 1 of his supplemental report that the data from his test "will be reported when complete." *See* Mot. Ex. C, Thames Supp. Report—Part 1 at 12. To the extent Plaintiffs seek to depose Dr. Thames on his supplemental test, Ethicon will make Dr. Thames available at a mutually convenient date.

For these reasons, Plaintiffs' argument that Dr. Thames's experiment is unfinished should be denied.

B. Plaintiffs' Arguments Regarding the Statistical Significance of Dr. Thames's Supplemental Tests Are Meritless.

Plaintiffs claim that Dr. Thames's supplemental report should be excluded because it lacks statistical significance. As discussed above, Dr. Thames will not opine at trial that his supplemental test proves that his cleaning protocol does not eliminate evidence of oxidation. Rather, Dr. Thames will only testify that his evaluation of a single sample of intentionally oxidized mesh exposed to certain aspects of his cleaning protocol did not show a reduction in oxidation. Given the limited purpose for which Dr. Thames will testify about his supplemental test, Plaintiffs arguments regarding statistical significance are without merit.

Plaintiffs also argue that because Dr. Thames supplemental experiment "uses only a single piece of Prolene mesh—whatever opinions he can garner from this experiment cannot be said to have any significance to the women implanted with the Prolene-based meshes that are part of this litigation." Mem. at 3. But Plaintiffs' argument misconstrues the purpose of Dr. Thames's supplemental test. Dr. Thames did not seek to evaluate *in vivo* conditions, and does not seek to offer any opinions about conditions in the human body based on his supplemental test. Rather, the purpose of Dr. Thames's supplemental test was to assess whether his cleaning protocol has any effect on scientific markers of oxidation, a point for which the replication of *in vivo* conditions would not only be unnecessary, but would potentially be a source of confounding factors.

In addition, Plaintiffs seek to support their argument by asserting that "as Dr. Thames states in his report 'at least 5 tests are required for statistical validity.'" Mem. at 3. Once again, Plaintiffs have taken Dr. Thames's specific scientific statements out-of-context in a misguided

attempt to raise doubts about his opinions. As his report plainly shows, Dr. Thames was discussing ASTM D638, a clearly defined standard for the testing of tensile strength. *See* Mot. Ex. B, Thames Wave 3 Report at 59 (citing ASTM D638, “Standard Test Method for Tensile Properties of Plastics”). Because Dr. Thames’s supplemental test was not testing tensile strength, neither the ASTM standard nor Dr. Thames’s statements about it are material to his experiment.

C. Dr. Thames’s Supplemental Test is Reliable.

Plaintiffs argue that Dr. Thames’s supplemental test is “scientifically unsound” and irrelevant because “it is not related in any way to how these meshes are actually oxidized inside the human body.” Mem. at 3. As discussed above, however, Plaintiffs’ argument misapprehends the purpose of Dr. Thames’s supplemental test. Dr. Thames did not need to replicate *in vivo* conditions to answer the more basic question of whether his cleaning protocol was capable of reducing or eliminating evidence of oxidation on Prolene. In fact, conducting the test under *in vivo* conditions would possibly introduce error into the experiment.

Plaintiffs also claim that Dr. Thames’s test is a “rigged game” because he oxidized the sample in its entirety, rather than merely the surface, so that “even *if* his cleaning protocol is destroying and removing the surface of the mesh, whatever remains after cleaning is *always* going to register as being oxidized.” Mem. at 4.²

Plaintiffs’ again misunderstand the science underlying Dr. Thames’s methods. Although it may seem logical to a lay person that removing the top layer of a completely oxidized fiber

² Plaintiffs’ also claim that Dr. Thames’s erred by using UV light to oxidize the samples, rather than a chemical oxidation solution analogous to the medium used by Dr. Steven MacLean in his control experiment. *See* Mem. at 4. Plaintiffs’ argument ignores the fact that while Dr. MacLean used a chemical solution on some samples, he also used UV light on other samples to ensure oxidation. *See* Resp. Ex. B, MacLean Wave 3 Expert Report at 55-64. Indeed, Plaintiffs disregard the fact that Dr. MacLean’s work showed that samples subjected to the chemical oxidation solution showed no surface cracking, which plaintiffs in pelvic mesh litigation have repeatedly argued is a hallmark of oxidative degradation. *See id.* at 59. In other words, Plaintiffs fault Dr. Thames for not using a method that would not have produced the conditions necessary for him to conduct his test. Plaintiffs’ argument makes no sense.

would expose more oxidized layers, this erroneous assumption fails to account for the tools Dr. Thames used in his test. Specifically, Dr. Thames used FTIR to assess the sample for oxidation, and so any reduction in the amount of oxidation would manifest in his FTIR data as a reduction in the intensity of the oxidation reading. Dr. Thames's data showed no such reduction of intensity, and therefore he concluded that there was no reduction in oxidation. Once again, Plaintiffs seek to substitute the speculative theories of their counsel for Dr. Thames's 50-plus years of education, training, and experience as a polymer scientist.

Although Plaintiffs seek to support this assertion by pointing to a study by Mary, their reliance is misplaced because the Mary study (i) used a different cleaning protocol than Dr. Thames, and (ii) is methodologically unsound. As an initial matter, the Mary study does not support the proposition that Prolene oxidizes and degrades *in vivo*. Notably, the authors did not test the mechanical properties of the sutures or conduct any molecular weight analysis, which even plaintiffs' materials scientists have conceded is required to establish that a polymer has degraded. *See, e.g.*, Resp. Ex. C, Mays 3/2/16 Dep. 79:3–80:12 (“Q. But, Doctor, for oxidative degradation to occur, there must be loss of molecular weight, correct? A. Yes, when oxidative degradation occurs, there is degradation of molecular weight.”); Resp. Ex. D, Jordi 10/30/13 Dep. 173:25–174:8 (admitting that test results showing no loss of molecular weight suggests that there is no degradation of polypropylene).

Instead, the Mary study concluded that the Prolene sutures had oxidized based on FTIR test results showing a peak at $1,740\text{cm}^{-1}$, which “has been assigned to carbonyl stretching, and identifies the presence of surface oxidation, because the chemical structure of both pure polymers are devoid of this functional group.” Mot. Ex. D, Mary at 201. But, as plaintiffs' materials science experts in pelvic mesh litigation have admitted, the authors did not recognize in

the study that 1,740^{cm⁻¹} is also the wavelength for one of the antioxidants used in Prolene. *See, e.g.,* Resp. Ex. C, Mays 3/2/16 Dep. 104:24–105:3 (admitting that one of the antioxidants used in Prolene has an FTIR signature of 1,740^{cm⁻¹}). Thus, because the authors failed to confirm that the peak at 1,740^{cm⁻¹} was evidence of oxidation, rather than a reading of the antioxidant package used in Prolene, the Mary study does not provide legitimate scientific evidence that Prolene oxidized *in vivo*.

In addition, Plaintiffs’ argument ignores the fact that the allegedly “degraded surface layer,” or “outer skin,” described in the Mary study is not Prolene, but a hardened shell coating the fiber due to the sample preparation process used by the authors. *See* Mot. Ex. B, Thames General Report, at 10–11, 15–23. The study explains that after explantation, the sutures designated for analysis using scanning electron microscopy were treated with either formalin or gluteraldehyde prior to cleaning. Mot. Ex. D, Mary Study at 200. As Dr. Thames has explained, however, formalin and gluteraldehyde crosslink with the proteinaceous layer on the fibers to form a hardened shell that can manifest as a cracked layer when viewed using scanning electron microscopy. *See* Mot. Ex. B, Thames General Report, at 10–11, 15–23 (explaining that fixative agents used in sample preparation—formalin, formaldehyde, etc.—bond or crosslink with proteins adhered to the surface of an explant to form a hard, insoluble, and brittle shell around the surface of the explant).

Moreover, the Mary study’s conclusion that “abrasive stresses, such as cleaning” cause flaking and separation of the outer layer from core of the fiber is inapposite to Dr. Thames’s cleaning protocol. Simply put, the authors of the Mary study did not use the same cleaning protocol as Dr. Thames. Indeed, the Mary study incorporated a harsh cleaning protocol that bears no relationship to the methods used by Dr. Thames. *Compare* Mot. Ex. D, Mary Study at 200

with Mot. Ex. B, Thames General Report at 103–04 (explaining cleaning protocol). For this reason, nothing in the Mary study stands for the proposition that Dr. Thames’s cleaning protocol removes evidence of oxidation.

In sum, Plaintiffs’ assertion that Dr. Thames’s supplemental test is scientifically unsound is entirely bereft of scientific support. Having failed to actually test Dr. Thames’s protocol, Plaintiffs offer only the conjecture formulated by their counsel with zero scientific support. Such speculation is insufficient to demonstrate that Dr. Thames’s cleaning protocol is unreliable, and the Court should deny Plaintiffs’ motion on this basis.

CONCLUSION

For the reasons stated above, and those articulated in Ethicon’s Response in Opposition to Plaintiffs’ Motion to Exclude the Opinions and Testimony of Shelby Thames, Ph.D. for Ethicon Wave 2 [ECF No. 2553], which Ethicon adopts and incorporates by reference, the Court should deny Plaintiffs’ Motion to Exclude the Opinions and Testimony of Shelby Thames, Ph.D. in Wave 3.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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